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## PATENT COOPERATION TREATY

**PCT****INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

|   |  |  |                       |
|---|--|--|-----------------------|
| Applicant's or agent's file reference<br>ON/4-33617A/USN  | <b>FOR FURTHER ACTION</b>  |  | See Form PCT/APEA/416 |
| International application No.<br>PCT/EP2005/001077  | International filing date (day/month/year)<br>03.02.2005   | Priority date (day/month/year)<br>04.02.2004 |                       |
| International Patent Classification (IPC) or national classification and IPC<br>INV. C07D401/00 C07D401/04  |  |  |                       |
| Applicant<br>NOVARTIS AG et al.   |  |  |                       |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> <i>(sent to the applicant and to the International Bureau)</i> a total of sheets, as follows:</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</li> <li><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</li> </ul> <p>b. <input type="checkbox"/> <i>(sent to the International Bureau only)</i> a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> |  |  |                       |
| <p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Box No. I Basis of the report</li> <li><input type="checkbox"/> Box No. II Priority</li> <li><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li> <li><input type="checkbox"/> Box No. IV Lack of unity of invention</li> <li><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li><input checked="" type="checkbox"/> Box No. VI Certain documents cited</li> <li><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</li> <li><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</li> </ul>   |  |  |                       |
| Date of submission of the demand<br>01.12.2005  | Date of completion of this report<br>30.08.2006  |  |                       |
| Name and mailing address of the International preliminary examining authority:<br><br>European Patent Office<br>D-80298 Munich<br>Tel. +49 89 2399 - 0 Tx: 523656 epmu d<br>Fax: +49 89 2399 - 4465  | Authorized officer<br><br>Samsam Bakhtiary, M<br>Telephone No. +49 89 2399-<br> |  |                       |

# **INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY**

International application No.  
**PCT/EP2005/001077**

**Box No. I Basis of the report**

1. With regard to the language, this report is based on

- the international application in the language in which it was filed
- a translation of the international application into , which is the language of a translation furnished for the purposes of:
  - international search (under Rules 12.3(a) and 23.1(b))
  - publication of the international application (under Rule 12.4(a))
  - international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements\* of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

### Description, Pages

1-13 as originally filed

## **Claims, Numbers**

1-7 as originally filed

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to sequence listing (*specify*):

4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

|                               |      |            |
|-------------------------------|------|------------|
| Novelty (N)                   | Yes: | Claims     |
|                               | No:  | Claims 1-7 |
| Inventive step (IS)           | Yes: | Claims     |
|                               | No:  | Claims 1-7 |
| Industrial applicability (IA) | Yes: | Claims 1-7 |
|                               | No:  | Claims     |

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Box No. VI Certain documents cited**

1. Certain published documents (Rule 70.10)  
and / or
2. Non-written disclosures (Rule 70.9)

**see separate sheet**

**Box No. VII Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

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**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Reference is made to the following documents:**

- D1: WO 03/066613 A (NOVARTIS AG; NOVARTIS PHARMA GMBH; LOISELEUR, OLIVIER; KAUFMANN, DANIE) 14 August 2003 (2003-08-14)
- D2: EP-A-0 564 409 (CIBA-GEIGY AG; NOVARTIS AG; NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHA) 6 October 1993 (1993-10-06)
- D3: WO 99/03854 A (NOVARTIS AG; NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHAFT MBH; ZIMMER) 28 January 1999 (1999-01-28) cited in the application
- D4: US-A-5 521 184 (ZIMMERMANN ET AL) 28 May 1996 (1996-05-28) cited in the application
- D5: WO 2004/074502 A (CIPLA LTD; KANKAN, RAJENDRA, NARAYANRAO; RAO, DHARMARAJ, RAMACHANDRA;) 2 September 2004 (2004-09-02)
- D6: WO 03/077892 A (NOVARTIS AG; THE UNIVERSITY OF MELBOURNE; GILBERT, RICHARD, ERNEST; KE) 25 September 2003 (2003-09-25)
- D7: WO 02/22597 A (NOVARTIS AG; NOVARTIS-ERFINDUNGEN VERWALTUNGSGESELLSCHAFT M.B.H; BUERG) 21 March 2002 (2002-03-21)

**2. Novelty**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-7 is not new in the sense of Article 33(2) PCT.

Document D1 discloses imatinib compounds in a salt form (see page 14, second paragraph). A list of specific preferred salts are disclosed on page 2, last paragraph.

The skilled person, by combining these 2 technical teachings, would in a clear and unambiguous manner, obtain the claimed salts of this application.

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The same goes for document D2 (see example 19 and the list of salts on page 3, lines 31-44).

**3. Inventive step**

In case the applicant amends the claims in order to restore novelty, then these novel salts would be considered as a invention selection from a broader family of salts as disclosed in D1 and D2.

Such a selection can only be regarded as inventive, if the claimed salts presents unexpected effects or properties in relation to the rest of the family.

However, no such effects or properties are indicated in the application. Hence, no inventive step could be acknowledged for any novel specific salts.

**Re Item VI**

**Certain documents cited**

Document D5 is cited as P category in the search report, in the european phase this document would become relevant regarding novelty of the claimed subject matter when the salt is HCl.

**Re Item VII**

**Certain defects in the international application**

Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1, D2 and D5 is not mentioned in the description, nor are these documents identified therein.

**Re Item VIII**

**Certain observations on the international application**

In case this application is proceeded in a european phase, then we draw the attention of the applicant that according Rule 29 EPC, independent claims 2,3,4,5 should be linked to claim 1.

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International application No.

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